312/1

1969

1146767 COMPLETE SPECIFICATION

3 SHEETS *This drawing is a reproduction of the Original on a reduced scale*

Sheet 1

Fig. 1

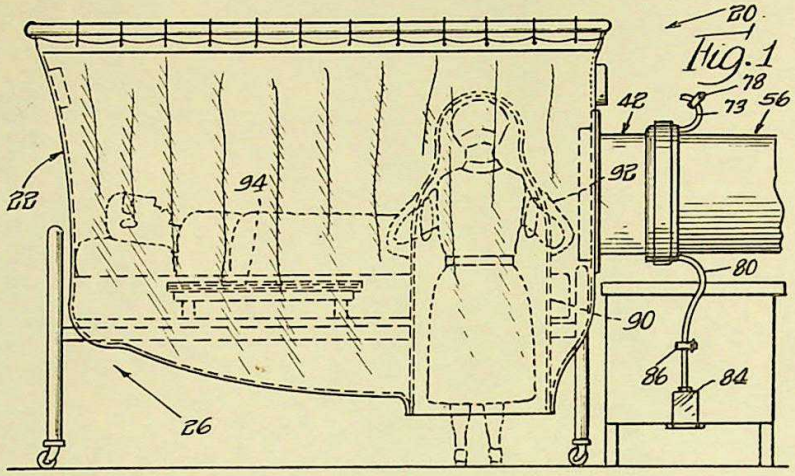


Fig. 2

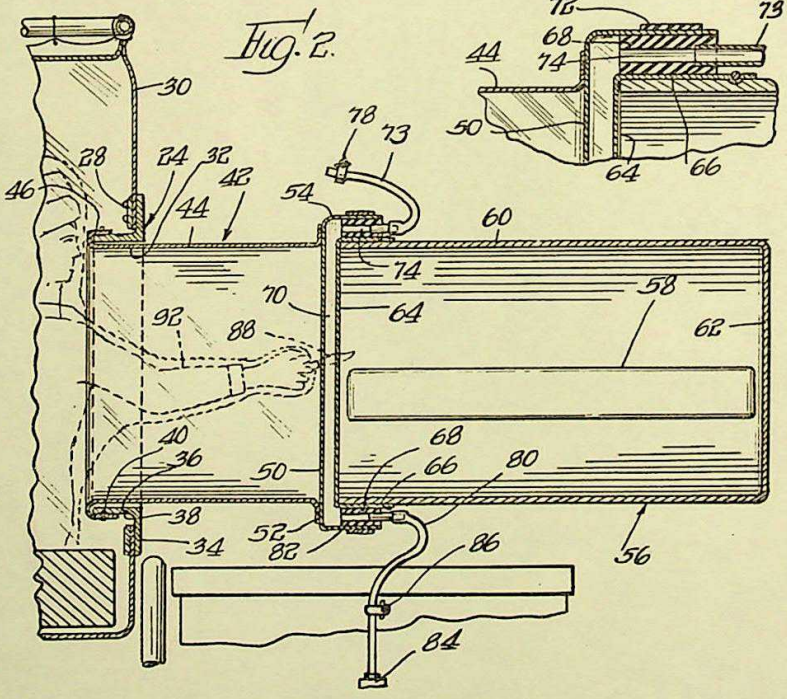


Fig. 3

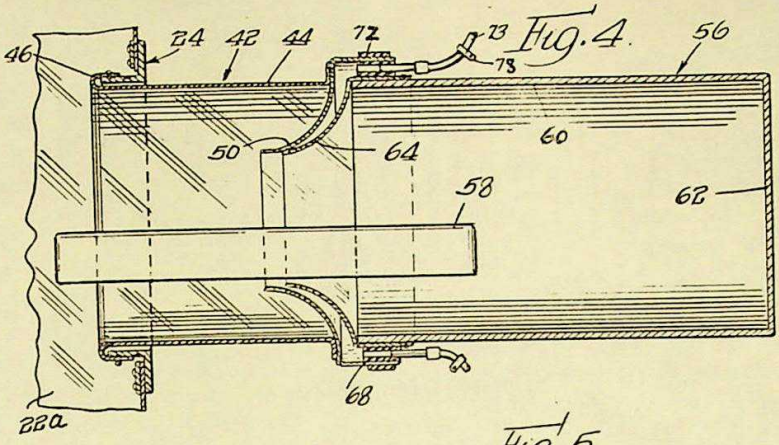


Fig. 4.

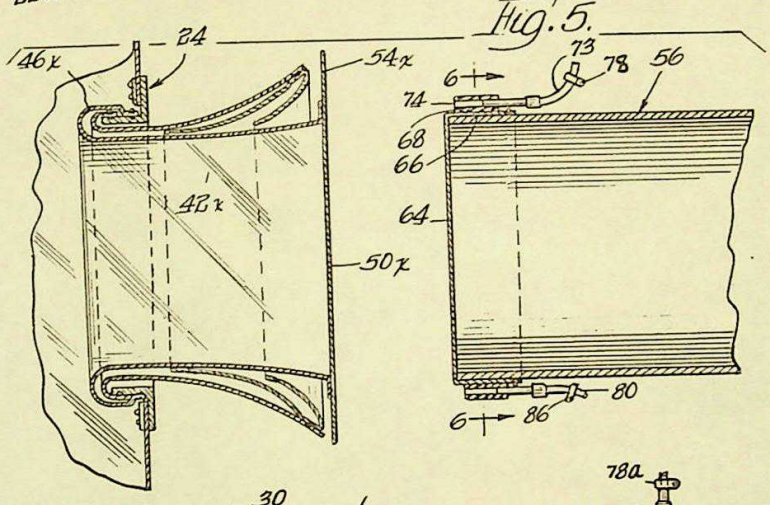


Fig. 5.

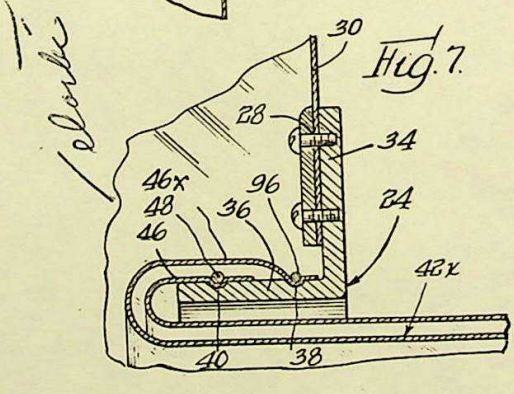


Fig. 7.

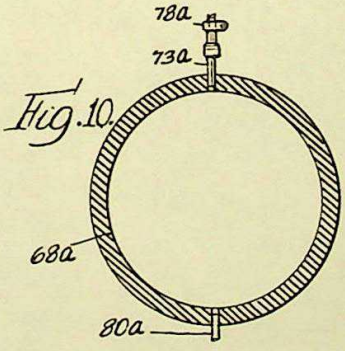


Fig. 10.

1146767 COMPLETE SPECIFICATION

3 SHEETS *This drawing is a reproduction of the Original on a reduced scale*

Sheets 2 & 3

Fig. 8

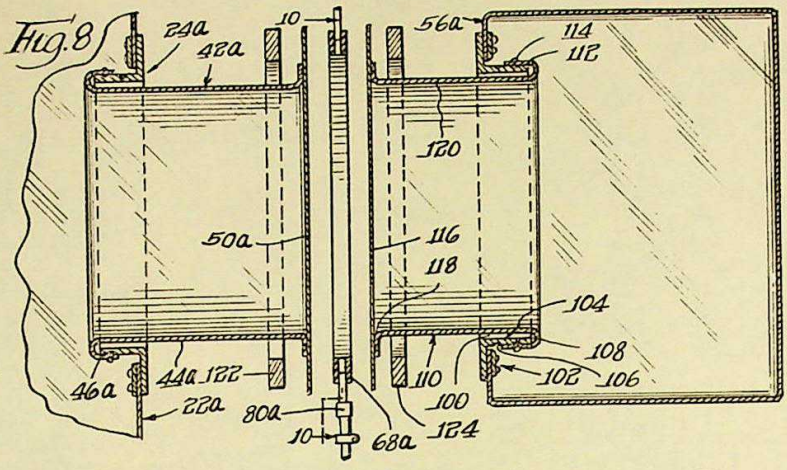
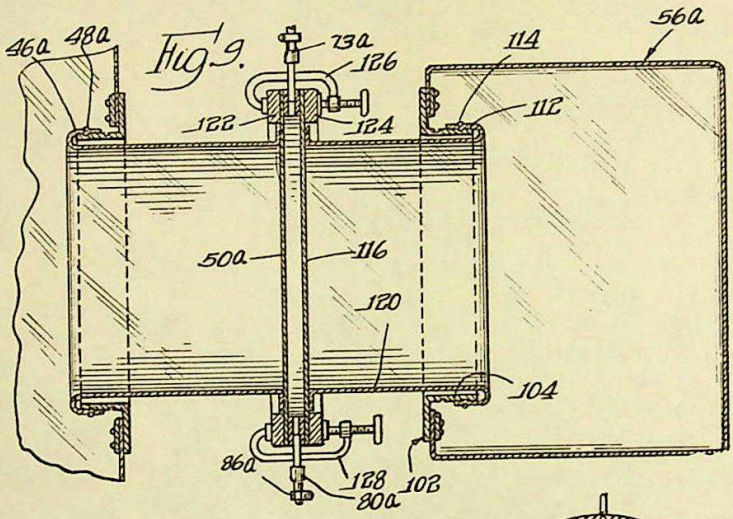


Fig. 9.



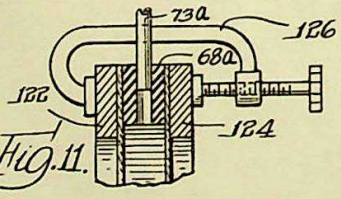


Fig. 11.

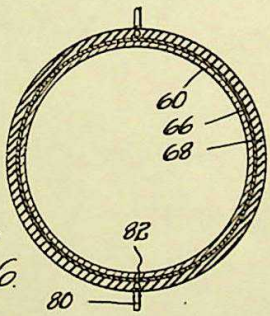


Fig. 6

PATENT SPECIFICATION

DRAWINGS ATTACHED

Inventor: PHILIP CHARLES TREXLER

1,146,767

1,146,767

Date of Application and filing Complete Specification: 5 Jan., 1967.

No. 678/67.

Complete Specification Published: 26 March, 1969.

© *Crown Copyright 1969.*

GREAT BRITAIN
GROUP
CLASS

Index at acceptance: —**A5** RB29

Int. Cl: —**A 61 g 12/00**

COMPLETE SPECIFICATION

Methods and Apparatus relating to Sealed Enclosures

We, SNYDER MANUFACTURING COMPANY, INC., a corporation organised under the laws of the State of Ohio, United States of America, of 1458 Fifth Street, New Philadelphia, Ohio, United States of America, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement: —

A variety of needs have arisen in medical, animal husbandry and certain industrial activities for the establishment and maintenance of a germ-free or otherwise uncontaminated and controlled environment within an enclosure. At the same time it is necessary to permit entry into and exit from the enclosure without enabling contaminants to enter the enclosure.

According to one aspect of this invention an isolating apparatus comprises a first enclosure having a member defining an access port, a closure member sealed in relation to the member and having a severable membrane, a second enclosure positioned adjacent the first enclosure and having an access opening, a second severable membrane sealingly closing the opening, means securing the membranes in adjacent opposing relationship and providing a seal around a space between the membranes, and means connected with the space for introducing a decontaminating substance into the space, the arrangement being such that the membranes can be severed to permit access between the enclosures through the space while maintaining the enclosures sealed from the surrounding atmosphere.

According to a further aspect of this invention, a method of establishing communication between first and second sealed enclosures while preventing contamination of the interior of the enclosures comprises the steps of: initially closing an access opening in each enclosure with means including a severable membrane, thereafter positioning the membranes in closely adjacent opposing relationship and sealing peripheral portions of the membranes with respect to each other and thereby providing a sealed space between the membranes, thereafter introducing a decontaminating substance into the space and decontaminating the opposing surfaces of the membranes, and subsequently severing the membranes and providing access between the enclosures. Examples of methods and isolating apparatus according to the invention will now be described, reference being made to the accompanying drawings in which: —

Figure 1 is a side elevation showing an isolating apparatus or isolator;

Figure 2 is an enlarged fragmentary partial section showing means for accomplishing entry into the isolator;

Figure 3 is an enlarged fragmentary section showing a portion of the isolator in greater detail;

Figures 4 and 5 are sections similar to Figure 2 and show successive steps in the method of transferring an article between the exterior and interior of the isolator;

Figure 6 is a section taken along line 6—6 in Figure 5;

Figure 7 is an enlarged fragmentary section of a portion of the structure in Figure 5 in order to show certain features in greater detail;

Figure 8 is a fragmentary section of a modified isolator and showing parts thereof positioned to be assembled together;

Figure 9 is a fragmentary section similar to Figure 8 and showing the parts in similar condition;

[*Price 4s. 6d.*]

Figure 10 is a section taken along the line 10—10 in Figure 8; and

Figure 11 is an enlarged fragmentary section similar to Figure 9 and showing features of the structure in greater detail.

In the drawings like parts are designated by the same numerals throughout the various Figures.

An isolating apparatus or isolator 20 comprises an enclosure 22. It is to be understood that a variety of enclosures may be used in accordance with the needs of a particular installation, but in each instance the enclosure has an access port 24. In the embodiment shown, the enclosure 22 is in the form of a plastics bag-like structure adapted to be associated with a hospital bed 26 for isolating a patient on the bed from the surrounding atmosphere. As will be understood, there are many instances when it is desired to prevent germs or other contaminants in the surrounding atmosphere from entering the enclosure 22. Suitable plastics for the enclosure 22 are for example polyethylene, polypropylene, vinyl resin, tetrafluoroethylene polymers, polyethylene terephthalate resins, rubber hydrochloride films and thermoplastic produced by the polymerisation of vinylidene chloride. The material used in any given instance will depend on the intended use and the desired clarity, ease of fabrication and bonding and elasticity.

The access port 24 is a relatively rigid and self-supporting member which is secured and sealed as at 28 to an end wall 30 of the enclosure 22. The port member 24 defines an opening 32 through the wall 30, which opening is large enough to permit food and other supplies to be delivered into the enclosure and material to be removed from the enclosure. Furthermore, it is contemplated that in certain instances the patient may even be moved into and out of the enclosure through the opening 32.

The port member 24 has a radially extending annular section 34 which is secured to the wall 30. In addition, the port member is provided with an axially inwardly extending annular flange 36. Annular grooves 38 and 40 are formed in an exterior surface of the flange 36 and in axially spaced relationship as shown best in Figure 7, for a purpose described below.

In order to seal the access opening 32, a closure member 42 is provided. The closure member 42 comprises a tubular section 44 formed from sheet material and preferably from plastics. An inner end marginal portion 46 of the tubular member 44 is adapted to be turned outwardly and reversely and assembled over the flange 36 of the port member 24 as shown in Figures 2, 4, 5 and 7. An elastic band 48 is assembled around the marginal portion 46 and engages in the groove 40 for securing and sealing the marginal portion of the closure member to the port member.

The internal dimensions of the tubular member 44 are approximately the same as those of the opening 32 and the tubular member extends outwardly a suitable distance through the opening 32 and away from the adapter or port member 24. An outer end of the tubular member 44 is closed by a generally flat transverse membrane 50 which is also formed from sheet material and preferably from the same sheet material as the tubular member 44. The membrane 50 is sealed to an outer end of the tubular member 44 as at 52. The membrane 50 has an annular marginal flange portion 54 extending outwardly from the seal 52, which flange portion may initially be in the same plane as the remainder of the membrane 50 as indicated in Figure 5 and is adapted to be folded to a generally axially extending position or it may initially be formed in such a position, for the purposes described below.

The apparatus also includes a second enclosure constituted by a container 56, which may be made from metal or any other desired material such as the material of the enclosure 22 in sufficiently strong form. The container is of a suitable size and shape for receiving an article 58 which is to be moved into the enclosure 22. The container 56 comprises a self-supporting generally cylindrical wall 60 and an end member 62 secured and sealed to an outer end of the wall 60. An opposite end of the container has an access opening which is initially closed and sealed by a membrane 64 formed from sheet material and preferably a plastics material. A marginal portion 66 of the membrane 64 is folded around the adjacent end of the container wall 60 and is secured and sealed thereto by an elastic or other clamping ring 68.

When it is desired to transfer the article 58 from the container 56 to the interior of the enclosure 22, the container is positioned as shown in Figures 1 to 3 with the end membrane 64 thereof in alignment with and adjacent to the end membrane 50 of the closure member 42. However, the container is positioned so as to leave a small space 70 between the membranes 50 and 64. Then the peripheral portion 54 of the diaphragm 50 is positioned over the elastic clamping ring 68 and is secured and sealed thereto by an elastic band 72 as shown in Figures 2 to 4.

The membranes 50 and 64 are adapted to be cut in the manner described more fully below in order to permit the article 58 to be passed through the opening 32. However, before the membranes are cut, care is taken to decontaminate their opposing surfaces, which surfaces are exposed to the surrounding atmosphere prior to assembly of the container with the closure member 42.

In order to introduce a sterilizing fluid into

the space 70 and thereby decontaminate the opposing surfaces of the membranes 50 and 64, an inlet tube 80 is connected with a passageway 82 extending through the relatively thick elastic clamping ring 68. The tube 80 is also connected with a bottle 84 or any other suitable source of supply for the sterilizing fluid. A hose clamp 86 is positioned on the tube 80 for controlling the flow of fluid. It is contemplated that the bottle 84 or other source of supply should be capable of delivering sufficient gas or liquid so as to fill the space 70 completely and thereby ensure complete sterilization of the membranes 50 and 64. Furthermore the bottle may be manually raised to an elevated position for filling the space 70 and then lowered to the position shown for draining the space.

A vent tube 73 is connected with another passageway 74 through the ring 68, which passageway is located at the upper side of the ring. The tube 73 has another hose clamp 78 positioned thereon. The hose clamp 78 is opened during filling of the space to permit all the air to be forced from the space 70. Then the clamp 78 is closed.

After the space 70 has been filled with a sterilizing liquid and the sterilizing operation has been completed, the upper clamp 78 is maintained closed and the other clamp 86 is open and the bottle 84 is moved to its lowered position. This permits the liquid to drain from the space 70 and at the same time draw a vacuum in space 70 so that the membranes 50 and 64 are forced together. This not only ensures complete draining of the space but also enables the connection between the container 56 and the enclosure 22 to be checked for leaks. Of course when the draining operation is completed the clamp 86 is closed.

After the membranes 50 and 64 have been sterilized, a knife 88 or other suitable instrument is employed for severing the membranes as indicated in Figure 2. The knife is maintained in a sterile condition within the enclosure 22 and may be grasped by an attendant through a flexible wall of the enclosure structure and manipulated in the desired manner. Preferably the enclosure structure 22 is formed with an integral jacket portion 90 having an arm and glove section 92 as shown in Figures 1 and 2, so as to enable an attendant not only to manipulate the knife 88 but also to reach into the container and extract the article 58 and otherwise administer to the patient in the enclosure. It is however, contemplated that, if desired, the arm and glove section 92 could be formed integrally with the tubular member 44.

After the contents of the container 56 have been removed, the access opening 32 may be re-sealed so as to enable the container to be withdrawn, and for preparing the apparatus for receiving material from another container. More specifically, it is contemplated that a supply 94 of a number of closure members 42 may be maintained in a sterile condition within the enclosure 22 as shown in Figure 1. Prior to removal of the container 56, an attendant removes a closure member designated 42*x* in Figures 5 and 7 from a supply pile and assembles the marginal portion 46*x* of the closure member 42*x* over the flange 36 and the marginal portion 46 of the original enclosure member. As shown best in Figure 7, the marginal portion 46*x* is extended over the flange until it overlaps the groove 38 and it is secured in the groove 38 by an additional elastic band 96. The original closure member 42 may then be pulled outwardly from the flange 36 of the port member 24 whereupon the closure member 42*x* may be extended to the position shown in Figure 5. It will be appreciated that, after the original closure member 42 has been removed, the marginal portion 46*x* and the elastic band 96 may be adjusted for engagement with the groove 40 in order to clear the groove 38 for accommodating another closure member after the steps of removing an article from another container have been completed. Of course, whenever necessary, the supply of closure members and elastic bands within the enclosure may be replenished by introducing the desired items in a sterilized condition from another container.

Figures 8 to 10 show a modified form which is similar to the structure described above as indicated by the application of identical reference numerals with the suffix *a* to corresponding elements.

In this embodiment the container 56*a* may be formed of self-supporting metal or other material or may be formed by a flexible sheet of plastics or other suitable material. Furthermore, the container 56*a* may be identical to the enclosure 22*a*. In any event the container 56*a* is formed with an access opening 100 which is defined by a port member 102. The port member 102 is essentially identical to but oppositely disposed from the port member 24*a*. Thus the port member 102 has an axially inwardly extending flange 104 formed with axially spaced annular grooves 106 and 108. The container 56*a* is normally sealed by a closure member 110 which is identical to the closure member 42*a* and has a marginal portion 112 secured to the flange 104 by an elastic band 114. An outer end of the closure member 110 is closed by a membrane 116 which is sealed at 118 to a tubular body 120 of the closure member.

In order to connect the container 56*a* with the enclosure 22*a* the outer ends of the closure members 42*a* and 110 are brought into alignment and adjacent relationship as shown in Figure 8, and a radially extending gasket 68*a* is positioned therebetween. The gasket 68*a*, like the clamping ring 68 described above, has sterilizing fluid inlet and outlet tubes 73*a*

and 80*a* connected thereto. The tube 73*a* is connected with a suitable source of sterilizing fluid. Clamping rings 122 and 124 are disposed for clamping the peripheral margins or radially extending flange portions of the membranes 50*a* and 116 against opposite sides of the gasket 68*a*. A suitable means such as C-clamps 126 and 128 may be used for holding the clamping rings, the gasket and the peripheral portions of the membranes in sealed relationship as shown in Figures 8 and 10.

After the closure members 42*a* and 110 are connected and sealed together, the opposing surfaces are sterilized in the manner described above in connection with the preceding embodiment. Then the membranes 50*a* and 116 may be slit for permitting transfer of items between the container 56*a* and the enclosure 22*a*.

There has been described a method and means for maintaining an isolated environment free of contamination while permitting entry thereto relatively quickly, easily and economically and without permitting the transfer of contaminants between the isolated environment and the surrounding atmosphere.

WHAT WE CLAIM IS:—

1. An isolating apparatus comprising a first enclosure having a member defining an access port, a closure member sealed in relation to the member and having a severable membrane, a second enclosure positioned adjacent the first enclosure and having an access opening, a second severable membrane sealingly closing the opening, means securing the membranes in adjacent opposing relationship and providing a seal around a space between the membranes, and means connected with the space for introducing a decontaminating substance into the space, the arrangement being such that the membranes can be severed to permit access between the enclosures through the space while maintaining the enclosures sealed from the surrounding atmosphere.

2. An apparatus as claimed in claim 1, and comprising means connected with the space for withdrawing the decontaminating substance from the space.

3. An apparatus as claimed in claim 2, in which the withdrawal means also evacuates the space.

4. An apparatus as claimed in claim 1 or claim 2 or claim 3, in which the membrane of the closure member includes an annular marginal portion, the means securing the membranes in adjacent opposing relationship and providing a seal comprising an annular member positioned against the second membrane and the annular portion of the first-mentioned membrane, and the means for introducing a decontaminating substance includes a passageway through the annular member, and means releasably sealingly clamping the annular portion to the annular member.

5. An apparatus as claimed in claim 4, in which the annular portion extends around and is clamped against a radially outwardly facing surface of the annular member.

6. An apparatus as claimed in claim 5, wherein the annular member has axially oppositely facing surfaces, the second membrane also including an annular peripheral section which engages the oppositely facing surfaces of the annular member, and first and second clamping rings respectively engaging and retaining the annular membrane sections against the opposite sides of the annular member, and means releasably securing the clamping rings together.

7. An isolating apparatus as claimed in claim 1 and substantially as hereinbefore described with reference to and as illustrated in Figures 1 to 7, or Figures 8 to 11, of the accompanying drawings.

8. A method of establishing communication between first and second sealed enclosures while preventing contamination of the interior of the enclosures, comprising the steps of: initially closing an access opening in each enclosure with means including a severable membrane, thereafter positioning the membranes in closely adjacent opposing relationship and sealing peripheral portions of the membranes with respect to each other and thereby providing a sealed space between the membranes, thereafter introducing a decontaminating substance in the space and decontaminating the opposing surfaces of the membranes, and subsequently severing the membranes and providing access between the enclosures.

9. A method as claimed in claim 8 and as hereinbefore described.

For the Applicants:
GILL, JENNINGS & EVERY,
Chartered Patent Agents,
51/52, Chancery Lane,
London, W.C.2.

Printed for Her Majesty's Stationery Office by the Courier Press, Leamington Spa, 1969.
Published by the Patent Office, 25, Southampton Buildings, London, W.C.2, from which copies may be obtained.